K122185

FEB 22 2013

510(k) Summary of Safety and Effectiveness

Submitted by:	United Orthopedic Corporation
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Date of Summary:	July 13 , 2012
Contact Person:	Fang-Yuan Ho Manager, Regulatory Affairs
Proprietary Name:	U-Motion II Acetabular System
Common Name:	Semi-constrained total hip prostheses
Device Classification Name and Reference:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis under 21CFR 888.3353 This falls under the Orthopedics panel.
Device Class	Class II
Panel Code	Orthopaedics Device
Device Product Code:	LZO, LWJ, KWY, MEH
Predicate Device:	1. "UNITED" U2 Acetabular Component (K050262) 2. "UNITED" U2 Acetabular Cup, Plasma Spray (K121777) 3. "UNITED" U2 Hip System (K111546) 4. "UNITED" Ceramic Femoral Head – Delta (K103497, K112463) 5. "Corin U.S.A" Trinity Acetabular System (K093472, K103518) 6. "Smith & Nephew" R3 Acetabular System (K061253, K070756, K092386 7. "Smith & Nephew" BIOLOX® Delta Ceramic Femoral Heads (K083762, K100412)

8. "Zimmer " Longevity® IT Highly Crosslinked Elevated Liners (K093846, K101229, K103662)
9. "Zimmer" Continuum Acetabular System—Bone Screw (K091508)

Device Description:

The subject device designed for total hip arthroplasty includes acetabular components and femoral components. The acetabular components are composed of a highly crosslinked ultra – high – molecular – weight - polyethylene articulating bearing surface fixed in a metal shell acetabular cup, while metal shell could be fixed with acetabulum by Ti Cancellous Screw and optional screw hole cover. The femoral component is composed of a ceramic femoral head.

U-Motion II Acetabular Cup includes U-Motion II HA Cup and U-Motion II PS Cup. It is manufactured from titanium alloy forging (ASTM F620) which are forged by titanium alloy bars conforming to ASTM F136. The outer surface of U-Motion II HA Cup is coated with dual coatings, CP Ti powder (ASTM F1580) for the inner layer and HA (ASTM F1185) for the outer layer. The materials of substrate and coating layers are identical to previous cleared "UNITED" U2 Acetabular Component (K050262, K121777). The outer surface of U-Motion II PS Cup is coated with CP Ti power. There are nineteen sizes of acetabular shell available, ranging from 44 through 80 mm outer diameter in 2 mm increments. U-Motion II Cup has a snap fit locking groove for acceptance of the U-Motion II XPE Cup Liner.

Clustered-hole and multi-hole series of U-Motion II Cup have shell holes for Ti Cancellous Screw fixation to the acetabulum. Ti Cancellous Screw are self tapping and in a 6.5 mm diameter with length of 15 to 60 mm in 5 mm increments. The designs of screw are identical with the cleared screws (K050262), except for the design of screw head. This

subject device also has screws and hole covers available to cover the shell holes if desired. Screw and hole covers are manufactured from Ti-6Al-4V bar (ASTM F136).

U-Motion II XPE Cup Liner is manufactured from highly crosslinked UHMWPE which conforms to ASTM F2565 and the UHMWPE raw material is in accordance with ASTM F648 and ISO 5834. The materials are identical to previous cleared "UNITED" XPE liners of U2 Hip System (K111546). U-Motion II XPE Cup Liner includes 0° and 20° hood designs, which are available in 28 mm, 32 mm, 36 mm and 40 mm inside diameter (ID). The 28 mm inserts fit the acetabular shells with outer diameter (OD) ranging from 44-80 mm, the 32 mm inserts fit the acetabular shells ranging from 48-80 mm, the 36 mm inserts fit the acetabular shells ranging from 52-80 mm, and the 40 mm inserts fit the acetabular shells ranging from 56-80 mm.

40 mm Ceramic Femoral Head – Delta is an additional size extension to the previously cleared "UNITED" Ceramic Femoral Head--Delta (K103497, K112463). The materials, design, safety and effectiveness of this subject are identical to the previously cleared device (available in sizes 28 mm, 32 mm and 36 mm), except for its larger diameter. 40 mm Ceramic Femoral Head – Delta, developed by CeramTec AG, is made from an alumina matrix composite in accordance with ISO 6474-2 and is available in –3, +1, +5 and +9 mm of neck length.

U-Motion II Cup will be used with U-Motion II XPE Cup Liner, 40 mm Ceramic Femoral Head – Delta, previously cleared 28 mm, 32 mm and 36 mm metal Femoral Head (K022520, K111546) and Ceramic Femoral Head (K103479, K112463) in corresponding size. This device should not be used with those of another manufacturer's hip components since the articular and dimensional compatibility cannot be assured. The 40 mm Ceramic Femoral Head may be used with UTF Stem (K110245) and the stems made of titanium alloy in U2 Hip Stem series (K003237, K062978, K111546).

Indications for Use:

The device is used for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
2. Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
3. Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
4. Correction of functional deformity.
5. Treatment of nonunion femoral neck and trochanteric fracture of the proximal femur with head involvement that is unmanageable using other techniques.

The device is intended for cementless use.

Basis for Substantial Equivalence:

The substantial equivalence of U-Motion II Acetabular System is based on its similarities in indications for use, design features, operational principles, and material composition to the predicate systems listed in the table below.

Current Subject	Predicate Systems	Manufacturer	Submission Number	Decision Date
U-Motion II HA Cup	U2 Acetabular Component U2 Acetabular Cup, Plasma Spray	United Orthopedic Co.	K050262 K121777	08/15/2005 07/18/2012
	Trinity Acetabular System	Corin U.S.A.	K093472 K103518	11/23/2010 03/09/2011

U-Motion II PS Cup	U2 Acetabular Component	United Orthopedic Co.	K050262	08/15/2005
	R3 Acetabular system	Smith & Nephew, INC.	K061253 K070756 K092386	05/31/2006 06/06/2007 11/03/2009
XPE Cup Liner	U2 Hip System	United Orthopedic Co.	K111546	07/01/2011
	R3 Acetabular System	Smith & Nephew, INC.	K061253 K070756 K092386	05/31/2006 06/06/2007 11/03/2009
	Longevity® IT Highly Crosslinked Elevated Liners	Zimmer, INC.	K093846 K101229 K103662	02/04/2010 12/03/2010 04/15/2011
Ti Cancellous Screw	U2 Acetabular Component	United Orthopedic Co.	K050262	08/15/2005
	R3 Acetabular System	Smith & Nephew	K061253	05/31/2006
	Continum Acetabular System	Zimmer, INC.	K091508	09/11/2009
40 mm Ceramic Femoral Head	Ceramic Femoral Head -- Delta	United Orthopedic Co.	K103497 K112463	03/04/2011 09/23/2011
	BIOLOX® Delta Ceramic Femoral Heads	Smith & Nephew, INC.	K083762 K100412	03/11/2009 05/05/2010

Performance Test – Bench:

This 5101k) was prepared in accordance with "Class II Special Controls Guidance Document- Hip Joint Metal Polymer Constrained Cemented or Uncemented Prosthesis",

"Guidance Document For The Preparation of Premarket Notification For Ceramic Ball Hip Systems", "510(K) Information Needed for Hydroxyapatite Coated Orthopedic Implants", and "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement". A review of the mechanical data indicates that the U-Motion II Acetabular System is capable of withstanding expected *in vivo* loading without failure. The following mechanical tests of the U-Motion II Acetabular System were performed:

- Evaluation of modified surface includes SEM evaluation per ASTM F1854, shear fatigue testing per ASTM F1160, static shear testing per ASTM F1044, static tensile testing per ASTM F1147, and taber abrasion resistance per ASTM F1978
- Locking Strength of XPE Cup Liner per ASTM F1820
- Wear Simulation Test of XPE Cup Liner per ISO 14242-1
- Range of Motion for XPE Cup Liner and 28 Femoral Head with +10 mm neck length by CAD simulation
- Evaluation of ceramic femoral head includes burst test, fatigue test, burst test for post-fatigue, rotational resistance test and pull-off test
- Evaluation of driving torque of Titanium Cancellous Bone Screw
- Characterize of material properties of XPE Cup Liner has been assessed in accordance with ASTM F2759.

A review of these tests has demonstrated that there are no new issues related to the safety and effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject devices.

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the U-Motion II Acetabular System. Based on the similarities to

the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to predicate hip systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 22, 2013

United Orthopedic Corporation
% Ms. Fang-Yuan Ho
No 57, Park Ave 2, Science Park
Hsinchu, 300
Taiwan

Re: K122185
Trade/Device Name: U-Motion II Acetabular System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, LWJ, KWY, MEH
Dated: January 10, 2013
Received: January 18, 2012

Dear Ms. Ho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510 (k) Number (if known): K122185

Device Name: U-Motion II Acetabular System

Indications for Use:

The device is used for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
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5. Treatment of nonunion femoral neck and trochanteric fracture of the proximal femur with head involvement that is unmanageable using other techniques.

The device is intended for cementless use.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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